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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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03/19/2005

Meong-Gun Song

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/508,746	Applicant(s) SONG, MEONG-GUN	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,10-13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 10-13, and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 3, 2008 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-7, 9-13, and 15-21 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 101

Claims 1, 3-7, and 10-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 lines 5, 8, 10, 12, 15, and 17 each contain a 101 error. Applicant has claimed a portion of the body which is considered non-statutory subject matter. For example, in line 5 applicant recites, "apparatus that uniformly stabilizes a diameter of an aortic annulus". This is positively claiming the aortic annulus as part of the apparatus. It is suggested to change the above to recite, --apparatus for uniformly stabilizing-- or --apparatus that is capable of uniformly stabilizing--. In line 8 applicant claims, "stabilizer which stabilizes the diameter". It is suggested to change the above to recite, --stabilizes for stabilizing-- or --stabilizer capable of stabilizing--. Similar errors occur in lines 10, 12, 15, and 17. Claims 3-7 and 10-12 depend upon claim 1 and inherit all problems with the claim.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 10, 11, 13, and 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the stabilizers" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is unclear which stabilizers applicant is referring to (claim 1 contains four different stabilizers). It is suggested to change the above to --ring stabilizers-- or something similar.

Claim 10 recites the limitation "the stabilizer" in line 3. There is insufficient antecedent basis for this limitation in the claim. It is unclear which stabilizer applicant is referring to.

Claim 11 recites the limitations "the ring type" and "the stabilizers" in lines 2 and 4 respectively. There is insufficient antecedent basis for these limitations in the claim.

Claim 13 recites the limitation "the aortic annulus" in line 6. There is insufficient antecedent basis for this limitation in the claim. Claims 15-19 depend upon claim 13 and inherit all problems with the claim. The same error occurs in claim 16.

Claim 15 recites the limitation "the stabilizers" in line 4. There is insufficient antecedent basis for this limitation in the claim. The same error occurs in claim 19.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 7, 10, 12, 13, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ablaza (US 4,190,909). Ablaza discloses an apparatus comprising an inner band stabilizer (14 or 18 or 14+18 on right side of fig.1), and outer band felt stabilizer (20, right side of fig.1), inner ring stabilizer (14 or 18 or 14+18 on left side of fig.1), outer ring felt stabilizer (20 on left side of fig.1), the rings and bands capable of providing the claimed function or placement. Ablaza discloses individual bands or rings (see figures). Ablaza discloses the inner band stabilizer or inner ring stabilizer (14 or 14+18) to be thinner (at groove 16) than surrounding area. Ablaza discloses the inner band/ring (14+18 or 18) and outer band/ring (20) to be a synthetic or biological material (col.2, lines 36-46). Ablaza discloses a method comprising implanting a band inner stabilizer (14 or 14+18 or 18) inside an aortic lumen (see figures 8-11; upper band shown placed in an aortic *lumen*), placing an outer band stabilizer (20) outside the aortic lumen (see fig.11; upper bands at an aortic *lumen*), implanting an STJ ring inner stabilizer (14 or 14+18 or 18) inside the sinotubular junction (lower ring placed at STJ in fig.11), placing a STJ ring outer stabilizer (lower 20 in fig.11) outside the sinotubular junction (see fig.11; upper bands at an aortic lumen, lower rings at STJ). Referring to the method claims, it is noted that placement is claimed generically an aortic *lumen*, not an aortic valve annulus, thus Ablaza reads on the claims since the upper ring/bands are considered to be placed in an aortic *lumen*.

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Claims 1, 3, 4, 5, 7, 10, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Chevillon et al. (US 6,511,506 B2). Chevillon discloses an apparatus comprising an inner band stabilizer (upper 150 or 150"; shown in fig.1 or 11), outer band felt stabilizer (upper 29; shown in fig.2), inner ring stabilizer (lower 150 or 150") and outer ring felt stabilizer (lower 29). Chevillon's rings and band are capable of the placement or use claimed. Chevillon's rings/bands (29, 150) are individual (see figs.1, 11). Chevillon discloses a sewing passage (holes; col.8, lines 40-42) that is thinner (thickness of zero, since holes are present) than a surrounding area (rest of inner band 150). Chevillon disclose three equally spaced markers (31, 330, 331, see fig.2) on the circumference of the rings. Chevillon discloses the bands/rings to be made of a synthetic or biological material (col.6, lines 1-25)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chevillon et al. (US 6,511,506 B2). Chevillon discloses the apparatus substantially as claimed (see above) having inner and outer bands (see band structure in fig.2) having vertical marks (330, 331) on both ends thereof and having extra margin portions (350, 351). Chevillon discloses the marks and margins substantially as claimed, however has not discloses the length of the margins (applicant has claimed 2mm). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have margins of about 2mm since wherein the general

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features are disclosed in the prior art (margins outside vertical marks they may be cut to tailor to the size of the vessel), it is not inventive to discover the optimum or workable ranges (length of 2mm) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chevillon et al. (US 6,511,506 B2) in view of Ablaza (US 4,190,909). Chevillon discloses a method substantially as claimed. Chevillon discloses implanting an inner band (upper 150) at the inside of a vessel and placing an outer band (upper 29) on the outside of the vessel at the location of the inner band (fig.1) and further implanting an inner ring (lower 150) inside the vessel at a different location and placing an outer ring (lower 29) outside the vessel around the inner ring (fig.1, 11). Chevillon discloses the bands to have vertical marks (330, 331) and margins (351, 350) at the ends of the bands. Chevillon discloses the method substantially as claimed, however does not disclose 1) the size of the margins and 2) the claimed placement of the rings in the aortic lumen and sinotubular junction. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have margins of about 2mm since wherein the general features are disclosed in the prior art (margins outside vertical marks they may be cut to tailor to the size of the vessel), it is not inventive to discover the optimum or workable ranges (length of 2mm) by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Further Ablaza teaches in the same field of ring implants for placement in aneurysm vessels, the placement at the sinotubular junction (lower rings in fig.11) and aortic lumen (upper rings/bands in fig.11). It would have been obvious to one having ordinary skill at the time the invention was made to combine Chevillon's method of inner and outer ring bands placed in aortic

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aneurysms, with Ablaza's teaching of particular placement at the sinotubular junction and aortic lumen (both locations with the aorta).

Claims 5, 11, 15, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ablaza (US 4,190,99) in view of Tremulis et al. (US 2003/0069593 A1). Ablaza discloses the apparatus and method substantially as claimed (see above), however does not disclose markers on the circumference of the rings. Tremulis teaches in the same field of ring implants for the vascular system, the use of three equally spaced radiopaque markers (62) on the ring implants in order to properly orient the implant and identification of attachment locations to the vessel (P0048; fig.10a). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Ablaza's ring implants with Tremulis's teaching of placing three radiopaque markers on ring implants in order to properly orient and identify attachment locations for the ring to the vessel.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738

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